

REMARKS

I. Introduction

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, a paragraph on page 16-17 has been amended.

Claims 2-3, 7-21, 23-27, 30-33, 36, 40-44, 48-50, 55-60, 65, and 69 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 1, 4-6, 28, 37-39, 45, 47, 51-54, 61, and 66-68 are currently amended.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1, 4-6, 22, 28-29, 34-35, 37-39, 45-47, 51-54, 61-64, 66-68, and 70-71 will remain pending in the application. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Specification

i. Sequence Listing

The Office objects to the specification because sequences appearing on pages 13-14 are not associated with sequence identifiers. Office Action, p. 4. Applicants direct the Office to the preliminary amendment filed September 7, 2001, where Applicants have amended Table 1 appearing on pages 13-14 to include sequence identifier information. These sequences are included as SEQ ID Nos: 2-33 in the sequence listing.

ii. Hyperlinked text

The Office objects to the use of hyperlinked text in the specification. Office Action, p. 4. Applicants have amended the specification in light of this objection. Applicants request reconsideration and withdrawal of the above objections.

b. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1, 3-6, 22, 28, 34-39, 45-46, 51-54, and 62-71 are rejected under 35 U.S.C. § 112, second paragraph as being allegedly indefinite. The Office requests clarification as to whether the substitution at position 129 in hPRL is in SEQ ID No: 1 or 34. Office Action, p. 4.

In order to further clarify the nature of the invention Applicants have submitted a new sequence listing. As explained previously, SEQ ID NO: 1 includes a leader sequence and this leader sequence is not present in wild-type hPRL. Thus, if the leader sequence were deleted, position 129 is a glycine. And for clarity sake, applicants submit herewith a new sequence listing with (SEQ ID NO. 35), which is drawn to a hPRL sequence without a substitution at position 129 and without the leader sequence. This sequence begins with a Leucine which is well known to a person of skill in the art as the first amino acid in PRL. For example, see Growth Hormone, edited by Harvey, et al., CRC Press, p. 7-8 (1995), submitted previously. Support for this sequence can be found in paragraph [0043], [0044], and Table 1 which provide a description of PRLs and their invariability at position 129. The new SEQ ID NO. 35 provides the sequence understood by a person of skill in the art to relate to hPRL described in the application.

c. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 1, 3-6, 22, 28-29, 34-39, 45-47, 51-54, and 61-71 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Office maintains that the Application is, “enabling for a method of treating prostate or breast cancers overexpressing the human prolactin receptor comprising the administration of a receptor antagonizing domain of hPRL of SEQ ID No: 34 with a substitution at position 129 conjugated or fused to a cytokine selected from the group of IL-2, IL-12, and IFN γ” Similarly, the Office maintains that the

Application is enabling for the treatment of prostate and breast cancer using substituted hGH. Office Action, p.5. In order to expedite prosecution of this case and without acquiescing to the Examiner's rejection, Applicants amended the claims to refer to treatment of prostate and breast cancer as well as the cytokines enumerated by the Office. In addition, Applicants amended the claims to refer to a receptor antagonizing domain that comprises SEQ ID NO: 35 but has an amino acid substitution at position 129. As the Office has conceded enablement, Applicants believe the amendment should overcome the Office's rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

Claims 1, 3-6, 22, 28, 34-39, 45-46, and 62-68 are rejected by the Examiner under 35 U.S.C. § 112, first paragraph for lack of written description. The Examiner asserts that no structure is used to define hPRL. Office Action, p. 2. As stated above, Applicants amended the claims to refer to a receptor antagonizing domain that comprises SEQ ID NO: 35 but has an amino acid substitution at position 129, which is a structural feature. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

d. Claim Rejections - 35 U.S.C. § 102

Claim 45 is rejected under 35 U.S.C. § 102(e) as being anticipated by Fuh (US 6,429,186). The Office has interpreted "another domain" as referring to a portion of the PRL protein. In the interest of expediting prosecution and without acquiescing to the Examiner's rejection, Applicants amended claim 45 to indicate that the other domain is a cytokine. As Fuh does not provide a method for inducing a response with a hPRL domain having a substitution at 129 and a cytokine domain, Fuh does not teach each and every element of the claimed invention. As such, Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

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Respectfully submitted,

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